AFTERNOON SESSION

---o0o---

EXCERPT OF THE CIC DISCUSSION ABOUT THE ACRYLAMIDE WORK PLAN AT THE OCTOBER 17, 2003 MEETING

to ten months before heading off to -- before proceeding with the work plan and defining a new NSRL.

CHAIRMAN MACK: And how would you answer the coalition of pregnant women who have read the Swedish studies and say, should I or should I not continue eating potato chips?

MS. CORASH: Well, I wouldn't substitute my judgment on that for that of FDA; and what I hear FDA saying is, on the science we have now, it's not changing its recommendations, which is eat a healthy diet, but it's not --

CHAIRMAN MACK: Whatever that --

MS. CORASH: -- issuing changes --

DR. MACK: -- that may be.

MS. CORASH: -- based on acrylamide.

CHAIRMAN MACK: The difficulty is, what is a healthy diet?

Thanks a lot.

MS. CORASH: Yeah, sure.

DR. MACK: I'm sure as hell glad I don't drive with her in the back seat.

Okay, we're going to take a five-minute bladder break, and then we're going to start the deliberations.

(Recess taken.)

DR. HERTZ-PICCIOTTO: Well, I just want it to

be recorded that I'm impressed with -- that this topic is so boring we couldn't get input, and I'm happy to try to lead off this discussion.

I think that we're in a sort of watershed place right now, or time, in chemical carcinogenesis and that it may well be that the findings on acrylamide might be part of the key to understanding something about the background rates of cancer in the human population which, up until now, has really remained a puzzle with many, many years of effort on the part of scientists in industry, government and academia mostly leading to identification of chemicals that don't explain a lot of the background risk, with the one exception being smoking and potentially PAHs and possibly some of the other constituents of cigarette smoke.

So I take this as being really an important point and a place where it's impressive that internationally and nationally the organizations involved in regulation and monitoring are taking this very seriously, and it is exciting the amount of research that is about to take place, and I think all of us are -- will be very eager to see what the results of this research leads to.

So, on the one hand, there's a question regarding what is the state of knowledge right now; and,

on the other hand, where might we expect to be in a year or two years from now. And I think that it's important to think about that second question in particular with regard to consideration of whether we should wait or not.

And I do want to point out that a decision to wait is, in fact, an endorsement of the current NSRL. That to not re-evaluate the NSRL is essentially to say that we are endorsing what exists currently on the books, and I think that we need to take that into account.

It seems probable to me that in two years from now or even in eight to ten months from now there will be some more studies and we will still be saying there's a tremendous amount that we don't know, that the gaps are -- may even increase. Of course, a little bit of knowledge always opens up other questions.

So to really sort of face where we are, we do have to think in terms of what answers are we going to get in the next few years that would enlighten us so much that it would justify not acting at this point.

I just want to make one comment in regard to the question of people's behavior changing in ways that could be harmful, and this is one of those arguments that one hears often, and, you know, I have a hard time

with that. It's hard enough to get people to change their behavior when we do have really solid answers.

We know that -- or we think we know that the diet with more fruits and vegetables and less of certain kinds of fats would be a lot better for the population, and we can't get people to do -- to move in that direction.

So, you know, I'm not really worried a lot that people are going to say, you know, the french fries out at you-name-your-fast-food-restaurant are so full of carcinogens, I'm going to go home and start cooking my own french fries.

My observation is that we've raised a generation of people who actually don't know how to cook at home anyway and -- speaking of my own kids, but -- probably some of them -- one of them. So I'm not -- I think that's not really the kind of concern that should dominate our recommendations.

Now, I'd like to suggest -- we don't have a huge amount of time and we have a lot of important questions to try to address, and I would like to propose that we divide the discussion into about four parts, I think.

The first thing I'd like to see us do is have a discussion about the scientific issues and -- separate

from the action, regulatory, and the particular work plan that's before us.

In particular, I'd like to address the carcinogenicity data and what are the relevant tumors here. Clearly, several authoritative bodies have evaluated this evidence and considered acrylamide to be a probable human carcinogen depending on the language, which body will give you slightly different wording there, but that, I think, is the basic idea.

Were we to accept some of the arguments that these are essentially all benign tumors, I think that would -- we would have to understand a little bit how it could be that those authoritative bodies have come to their conclusions, which doesn't mean that we might not want to disagree. We could. So I would actually like to settle that question with a little bit of discussion in a few minutes.

Then, if there's anything to say about the mechanisms with regard to either the metabolite question, glycidamide versus acrylamide, it appears to me that there's disagreement based on what's in the literature, and I think Tom did a very nice presentation about -- Tom McDonald -- about the state of the science on this -- on that point.

We might also want to discuss a little bit the

human data that are -- that have been published, the studies that are out there, and maybe the epidemiologists can at least clarify for the nonepidemiologists on the committee what we think about those studies.

Now, I understand we're not -- our committee is not directly responsible in any way for evaluating reproductive effects and that there isn't a committee under Proposition 65 dealing with neurotoxicity, and that does seem to be at this point possibly the most sensitive endpoint in human studies. At least that's the endpoint that's been observed very clearly in occupational -- occupationally-exposed cohorts.

And I think it's important to note that, although I think we don't have much legally we can say about that. That's my understanding, and I'm getting a nod here of the affirmative from the legal department.

So I'd like to discuss some of these scientific issues initially and see if we can come to, if not closure, some degree of higher understanding.

The second area I'd like to outline for discussion would be a discussion of the exposure information and a little bit of clarity here on average consumers. Maybe we'd like to have some discussion about the -- what we might like to see OEHHA produce in

regard to exposure assessment.

And I would like to suggest that we not limit that to food, but I would love to see the comparative data relating to water and personal care products, which also seem to be another source, and then that relates back to the question of absorption, dermal versus oral absorption.

Then, from there, I think we could then proceed into a discussion of the specific work plan issues, and the first one being the NSRL, and I'd like to -- maybe at that point I'll make some comments to lead off that discussion.

The item three in the work plan, which had to do with alternative exposure levels -- and I think that's related to the NSRL, although they're not the same question -- and so I think we should start at that point, the NSRL, and then discuss this issue of alternatives.

And the warning label question then would be -- and the detection method would then be the last two items I think we should discuss.

So that's the order I would suggest we proceed under. So, Mr. Chairman --

CHAIRMAN MACK: I think you set out a perfectly appropriate order, so why don't you start discussing

them, and you may stop for further comments from the rest of us at your leisure.

DR. HERTZ-PICCIOTTO: Okay. Well, I think the first question, actually, I would like to have clarification on and hear from the toxicologists is the relevance of the tumors that have been seen in the major carcinogenicity bioassays, and we've read comments and heard comments about the benign nature of the tumors.

There are the thyroid adenomas, there are the mammary tumors, there are some -- I have them here in front of me -- benign tumors, there are the adeno tumors, there are some mesotheliomas of the testis and a few others.

So maybe Joe or Jim or -- would like to make some comments on that issue.

DR. FELTON: I'd defer to --

DR. HERTZ-PICCIOTTO: You defer to Joe, okay.

DR. LANDOLPH: Well, it's already listed. You know, the EPA has listed it as a Group 2-B probable human carcinogen, so I wouldn't presume to think past that. That's already been an expert body that's done it. IARC calls it Group 2-B, which is possibly carcinogenic. That probable/possible is a continuum and many chemicals fall into that.

I was impressed, I would have to say, with the

study by Johnson, which was the Fischer 344 rat study,

because they did it by relevant mode of administration, which is in drinking water for two years, and they got a number of different tumors:

Tumors of the adrenals, the mesotheliomas, the follicular adenomas, thyroid tumors, and central nervous system tumors in the males, pituitary adenomas, thyroid follicular tumors, mammary adenomas and adenocarcinomas, oral papillomas and uterine adenocarcinomas in the females. So that's a lot of different tumors at different tumor sites, both benign and malignant.

So that seems like a nice model to start from, particularly because it uses the mode of administration through the oral route, which is as relevant to humans as you can get, although it's drinking water rather than a feeding study, but it's still an oral route.

So it -- this looks like it has a reasonable database behind it. Some of the tumors certainly are benign, that's true, but this practice of adding benign and malignant tumors together is common in that -- in the regulatory literature.

DR. FELTON: I think what it's really going to come down to as we -- you know, as we get into this is, what do the shapes of these dose response curves look like?

And, you know, is this the type of thing where we're going to have the data that we need to start to

look at the no effect levels very carefully and mechanistically.

And if we have the kind of tumors that we could suggest that they aren't linear, that there is a threshold, then that's important. If we decide that the tumors really don't, that these are -- that we're going to get a linear response in carcinogenicity, then I think we don't need to discuss it any further.

Now, obviously, Dr. Friedman brings up the point that some of these tumors may have some different mechanisms of formation and may not be linear, and to me that's important, although those aren't the only tumors that have been seen.

So I think what our discussion should really be is focused around how do we get at this risk assessment the best way we can, and I don't think anybody here would disagree, Joe, that, yeah, there's a lot of tumors and that's why it's listed.

DR. HERTZ-PICCIOTTO: Okay. It sounds like that's not particularly controversial.

How about if we have a little discussion about the exposure issues and what are the -- what is it -- what information about exposure is going to be relevant

that OEHHA should be considering in develop -- in its next steps. Not a clear question, I guess.

Jim.

DR. FELTON: Well, I mean, we can do a lot of analytical chemistry, and it's been done very well, and I'm sure we're going to get numbers that are going to vary over mean, but we're going to come up with some numbers that we can be pretty confident that we're going to see in the different types of foods.

The next question, of course, for risk assessment is, you know, who's eating those foods at what age -- we've already gotten into all this discussion -- but what we really need is exposure information which, even though everybody talked about all the stuff that's coming out, I don't think if we wait a year from now we're going to have good exposure information at different ages and different types of diets. That's hard to get, as you know. So that's where I think the emphasis has got to be.

CHAIRMAN MACK: It seems to me that the most important piece of information about exposure that we have currently is that it's highly variable. That with -- going from one McDonald's to another or two doses of the same brand of potato chips, there are big differences.

We know that there are differences in the consumption of what are generally recognized to be relatively high dose foods in the population by ethnicity, by social class, by lots of different such

things, and certainly by age.

So that the typical person, from the standpoint of the past regulation issues, is a much different kettle of fish or a much more difficult thing to deal with than they have been in the past because there are big differences within families and between families.

So I think the very fact of this variability is something that's really important. Now, I'm first to recognize that we don't know exactly how variable it really is.

We don't have good assessments. We don't have good sampling methods. It will take time to work all those things out. But as of right now, we know that there are things which are carcinogens which are highly variable from food to food and highly variable in the population as well.

DR. HERTZ-PICCIOTTO: Well, let me pose this. Food is something we eat every day, several days -- several times a day --

CHAIRMAN MACK: Some of us more than others.

DR. HERTZ-PICCIOTTO: -- and -- you said it.

So the variability in -- in the food products would seem to me to average itself out if we have good estimates of what people's intake of the foods are.

That, you know, today's french fries and tomorrow's french fries might differ, but -- the

likelihood that one person is going to get the highest batch of french fries day after day after day is low relative to the variability -- the potential variability in -- you know, some people eat french fries 15 servings a week, you know, some college students versus maybe hopefully other people may be eating it somewhat less.

So the variability within the food supply for a given food item would strike me as being less important than characterizing what the variation is in human food consumption.

CHAIRMAN MACK: I really don't think you can assume that. I think certain people like their french fries crisper, some people like their meat more caramelized and well done, other people like it -- like it rare.

And there may well be taste differences which proceed over the lifetime, and so not only will there be variability by food, in my opinion, there's very likely to be variability in preference. So I don't think we know. What you say is -- may be reasonable,

but it may not be.

DR. FELTON: My question is: Can you take all that variability -- and this is for you guys -- and put that all into your risk bounds that you work on? I mean, is that useable?

DR. HERTZ-PICCIOTTO: If you have the

information and you can characterize what that variance is in human consumption, then, yes, you could.

I mean, if you can characterize here's the bottom 2.5 percent, here's the top 2.5 percent, here's the median, then, yes, you would be able to plug that into your formulas and determine what the variation is then in risk level.

And it -- I mean, it's also important to know what that variation is in order to determine how well epidemiologic studies will be able to detect and define any carcinogenic effects or other health outcomes, for that matter, in relation to acrylamide.

Because if there's not sufficient variability, then epidemiology isn't going to go anywhere with telling you anything about the health effects from acrylamide. You have to have variation; and if the variation is insufficient, you won't be able to see an effect.

CHAIRMAN MACK: But I think you were asking

about the modeling for purposes of regulation, and there we used a convention of one case per 100,000 people, and here we have a situation where one has to ask 1,000 of what -- 100,000 of what kind of people? 100,000 children from 0 to 5? 1,000 -- 100,000 pregnant women? Are you -- are you going to simply take the average and leave it go at that?

And I really think we're in a situation here where the usual kind of regulation guideline is not very useful because neither do we know the distribution of exposure in the population nor do we -- can we specify with any degree of accuracy what the number of cases per hundred thousand of the average population is. It will, of course, depend on the age distribution, et cetera, et cetera, et cetera.

But the answer to your question is, you have to do -- you have to put it in if you're going to use that methodology.

DR. HERTZ-PICCIOTTO: Actually, I think this is a perfect lead-in to a discussion of the revision of the NSRL, and we heard several presentations this morning relevant to that; in particular, the one from Dr. Hattis about what sorts of things could go into the -- given current day information as of today -- into a revised NSRL.

I think it's important to recognize that there -- we're all in a situation of shifting sands and that what's -- what information we have today, it's going to be somewhat different, you know, next month. There may be even more papers out on pharmacokinetics by early 2004, we may have further data, and so on.

Nevertheless, the question before us is whether we want to recommend that OEHHA go ahead with a revision

of its NSRL; and as I said earlier, I think to not ask them to do that is actually to endorse the current NSRL, and I think that would be remiss because we do have a considerable amount of new information from the time that that one was derived.

Comments from the other committee members?

CHAIRMAN MACK: I certainly agree. I don't think there's any option but to try and revise it because, just as you say, not to do so is the -- is an acceptance of the current one.

Where I have comments is about the third part of the work scope, which is an alternative NSRL, but I don't know if you want to do that yet.

DR. HERTZ-PICCIOTTO: No, I think we should stick with these questions, take them distinctly as they are.

CHAIRMAN MACK: Let's force everybody else to

express an opinion on altering the NSRL.

DR. FELTON: I agree.

DR. GOLD: I think we all agree that -- or maybe I shouldn't speak for the group -- that we need to take a look at revising it, but I think we want that informed by additional information, and we heard a lot about studies that are underway and how we should wait for them.

I noticed kind of a minimal amount of human

studies mentioned. There are a lot of laboratory and mechanistic studies and so forth, which are very important, but if we want to have some information on what happens in humans and six months or a year from now not being in the position of saying we still have this problem of extrapolation from animal studies to humans, then we have to, I think, encourage a collection of data in humans.

And I saw a reference to the NHANES, which certainly will be helpful as long as it is not restricted to just adults, for example. There is a component of the NHANES that looks at young folks, and that would be a good thing to include.

And that we not try and ask OEHHA to come up with this sort of a summary measure, but to examine intakes across a wide spectrum and give sort of ranges

and so forth in various subgroups of the populations to the extent that it's possible. I'm not sure how much is possible.

DR. FELTON: I'd like to reiterate what you said, Dr. Gold. I think what we're missing here -- I mean, you looked at all the gene tox data and the animal data, and we can refine all that, but we're just so short on good human data it's really hard.

I'd love to know before I go home why the 8,000 people in the acrylamide plant didn't come down with any

significant tumors. Maybe you guys can tell me that before we go.

But the main thing I want to say about the NHANES -- and that's what I'm getting at -- is we tried to use this for years for our heterocyclic amine data, and the most unfortunate thing is it doesn't really tell you about cooking parameters.

And here, for these compounds, cooking parameters are going to be important. You know, was it cooked in fat? Was it cooked in the frying pan? Was it cooked burnt brown? Was it lightly cooked? And those are going to be huge when we try to get exposure assessment, and that data, to my knowledge, is not -- at least the last time I looked at NHANES wasn't there.

DR. LANDOLPH: I guess I would certainly

recommend going ahead slowly, carefully, prudently. It will take quite a while to make a new document anyway, and I think you certainly should get the results of the JIFSAN meeting in April of '04 and incorporate as much of that data into any new NSRL as you possibly can.

And I appreciate Jim's comment. Again, I would consult your expert epidemiologists and see if you can at least use that data to get some upper bounds to the data and try and incorporate that into the document wherever possible.

And I certainly laud Dr. Denton's letter to the

FDA where it indicates you're going to partner and work with them because I think it's very important.

This seems like such a big issue, it's good to have a consortium working on it, although you may diverge in your opinions later, but I certainly would take advantage of all their expertise and their ongoing effort in this area because it's just too big a job to do on your own.

So I certainly would recommend partnering with them and getting all the help you can. Not only from them, but also perhaps from WHO or other agencies involved in this.

DR. GOLD: This sort of -- the next point -- kind of goes back to your issue about exposure

assessment, but maybe the colleagues on the committee could comment on the contention that the adduct information is a good surrogate measure of exposure.

And the reason I bring it up is to again exhort the agencies and the powers that be that we need human data, and there are repositories around that could be exploited for looking at adducts potentially if there was some sort of initiative from the appropriate agencies.

So if, in fact, that's a good measure, which I'd like to hear about, then what's the possibility of using some of these repositories to again inform the

decision making.

DR. FELTON: I could comment on that as far as the adducts go. I mean, the darn trouble is they're the best measurement we've got, but they're not good enough, and that's what we always run into with adducts.

We'd love them to be totally related to risk and just many times they aren't, but we don't have anything better as far as exposure or risk, so we use them. And we do everything, P32 post labeling, accelerator mass spectrometry measurements, other types of measurements, to get at these levels in humans that have been exposed.

I think with acrylamide we're going to have

levels that are going to make adduct work fairly doable, but we've got to be careful what it means.

DR. GOLD: I wasn't commenting really on a sense of getting an estimate of risk, more using it as an assessment of exposure. And I think it ought to be explored for that purpose.

Given that all these other -- every data set is going to have its limitations so -- the NHANES is not going to tell you how the food was prepared, but maybe the composite of putting these different sources of data together would round out the picture so it would be more informed than it currently is.

DR. HERTZ-PICCIOTTO: I would guess that if the

NHANES database could be used to evaluate the hemoglobin adducts and look to see whether it correlates at all with self-reported intake, if it does, then that's important information. If it doesn't, that's also important information.

If it can be a surrogative dose telling us that self-reported exposure isn't the way to go, then that would be useful for designing future studies to evaluate risk in relation to acrylamide internal dose.

So I don't know exactly what -- whether that's possible with NHANES, but that would be one -- you know, one database. And, of course, there's many others.

CHAIRMAN MACK: I was just going to say that even before the self-reported dose issue is the feeding studies of people who are given chips ad libitum to see whether or not that, in fact, changes the adducts, and I gather from Dr. Troxell that that's the sort of thing that is going on now and that would be the first piece of information that is pertinent.

DR. DENTON: Regarding the timing on the NSRL, there was some discussion about -- as you know, that our current NSRL was based upon the US EPA IRIS number. As I understand it, the US EPA is going to be revising that IRIS number.

George, do you or Tom know anything about the timing of that or whether the recommendation of the

committee -- I guess the relative importance of that revision, should it or -- should it be happening as the basis of the NSRL.

DR. ALEXEEFF: Just as a comment, there's really no way to predict when US EPA will come out with an assessment. I mean, there are some assessments we've been waiting for several years that were supposed to be done several years ago. So it could be soon. It could be a long time.

DR. HERTZ-PICCIOTTO: Another comment in regard to the NSRL would be to investigate the possibility of

using the human studies that exist to calculate upper bounds, and I think this was mentioned by a couple of people earlier today. The Marsh study, I think, might be useful in that regard.

The problem with the Mucci study is the particular endpoints they used, it's unclear whether those are of relevance. They're not endpoints that were observed in any of the animal studies, although I suppose the same thing could be said in regard to the pancreatic tumors that were seen in the Marsh study.

So -- in any case, I think this is worth investigating, the fact that there is some human data out there, and you might also look at the Schultz re-analysis, which I happen to be a co-author on, of the Marsh data in regard to the pancreatic cancer to see if

those data would be useful.

Jim, you asked the question about the Marsh data and why a cohort of 8,000 people didn't show any excess. You know, the study is interesting. I had some questions about some of the methodologic issues in that study, although one of them may not be a particularly big deal.

It is notable in that study, interestingly, that there was no excess of non-malignant respiratory disease, which suggests that -- in fact, there seemed to

be a little bit of a deficit, which suggests that there were fewer smokers than is typical in the general population in that cohort, and that's somewhat unusual for occupational studies, but it does suggest that the pancreatic tumor excess could not be -- is probably not explained by smoking.

And the other reason why I wouldn't expect that that was explained by smoking is that the dose response was internal to the cohort as well, which it's generally been seen, and this has been studied in many, many occupational cohorts that smoking doesn't differ a whole lot from one exposure group to another within a cohort.

An adjustment for smoking, when it is collected, has -- makes very little difference in occupational carcinogenesis studies, is not big enough to account for what's seen here, which was over twofold

in the highest dose group.

Just a few days ago I was at a meeting of the Board of Scientific Counselors for NTP and we were evaluating lead, and the literature on lead is quite the opposite, where all of the risks are in the order of about 1.3-fold relative risks, and that's a case where -- and there were no internal comparisons that were done.

In that situation, it's easy to speculate and

it's quite plausible that smoking could account for the excess that's observed, but in this case it does not appear that that would be -- that would be the case.

DR. FELTON: Can I ask you just a little quantitative part of the whole thing, which I tried to do but it's not my expertise, so -- the dose that the people in the work place environment got, although it was presumably pulmonary rather than oral versus what we might think somebody ate for that same period of time that they worked there in french fries, is there any way we can use that kind of data to look at human risk?

DR. HERTZ-PICCIOTTO: Yeah, you could. And I actually want to retract my back-of-the-envelope calculation that I reported a little while ago because I think I may have done that wrong. That's the -- one should never report back-of-the-envelope calculations.

I think the best information we have on that

right now is what Dr. Hattis presented earlier in which he did the calculations to suggest that the power of that study would have been adequate to see a 40 to 70 percent excess, if that's -- if I'm remembering correctly what you said.

DR. HATTIS: That was the Mucci study.

DR. HERTZ-PICCIOTTO: In the -- oh, that was in the Mucci study; not in the Marsh study.

DR. HATTIS: I think that they're -- I have done calculations from the Marsh study. I don't remember them precisely enough to report.

I think our very highest group might have some excess over the dietary, but the dietary background would be expected to obscure some of the differences in the lower dose groups.

DR. HERTZ-PICCIOTTO: But this is definitely something that we can ask OEHHA to clarify in developing their new NSRL, to take into account what really -- and that sort of falls under the category of what I said earlier, which is to use the epi data to construct an upper bound and really determine what -- is the upper bound based on what the exposures were in that study, and that might include also determining what we know about inhalation versus ingestion, where inhalation did seem to be the main exposure route, although potentially there was dermal exposure as well.

And I did see some studies on pharmacokinetics related to absorption by the dermal route, but I don't remember seeing anything in this pile about inhalation, so I don't know if those studies have been done, and I don't know if anything is planned on looking at inhalation since the main concern here is food, but it certainly would help in the interpretation of the

occupational studies.

DR. GOLD: Can I just say one thing, though, about the human studies. I think it's good to use them but not to restrict the investigation to the ones that are published so far in this question.

I think the Marsh study has limitations of size. I mean, there are less than five testis tumors and thyroid gland tumors, which suggests the original sample size was just too small to look at some of the relevant tumors.

Some of the other studies that we were given to examine, I -- as you alluded to, weren't necessarily looking at the appropriate sites.

There are other human studies out there that have -- there's a large international brain tumor study, for example, that might be accessed for a purpose like this and whether -- I don't recall whether the dietary data would be sufficient, but I know they were very interested in diet.

So that there are other data sets out there that should be explored and not restricted to the few here that have admitted limitations -- severe limitations.

DR. HERTZ-PICCIOTTO: I think it would be very useful to have some epidemiologic data on some of the

female cancers since both mammary and uterine tumors were observed in animal studies.

DR. SPANGLER: Well, you know, there was one uterine tumor seen in the rat study.

DR. HERTZ-PICCIOTTO: There were seven in the high dose groups.

DR. SPANGLER: In Johnson?

DR. HERTZ-PICCIOTTO: There were five in the high dose group, total, rats with an adenocarcinoma, metastatic or nonmetastatic, of the uterus. Five in high dose group, and then the other dose groups were 1, 2, 1 and 0 for those four. On page 160 of Johnson.

DR. SPANGLER: Okay. I see that.

DR. HERTZ-PICCIOTTO: Okay. Anything else we want to say about the revision of the NSRL?

CHAIRMAN MACK: I guess I just have a lot less confidence in the Marsh study than you do. The relative risk for pancreas cancer is 1.25 and for deaths it's 1.36, and they looked at all tumors without an -- a prior hypothesis.

DR. HERTZ-PICCIOTTO: The dose response analysis goes 0.8, 1.7, 1.5, 2.3. 2.3 in the highest dose group. And then in the next analysis by cumulative exposure it's 1. -- I'm sorry, my eyesight is going -- but the top one is 2.6. And I won't quote from our

re-analysis.

Okay. Why don't we move on then from the NSRL to the question of -- and these are sort of -- there are sort of two issues, I think, that are somewhat linked.

One is this issue of developing an alternative NSRL as outlined in point No. 3 of the work plan, which says: Identify acrylamide levels in foods below the limit of detection (regulation) -- I'm sorry. Wait a minute. I'm sorry. I'm reading No. 2.

No. 3: Identify alternative acrylamide exposure levels for certain foods based on public health considerations.

So OEHHA proposes to develop alternative regulatory levels and develop a regulation listing acrylamide concentrations in such foods deemed to meet the exemption requirements of Proposition 65.

And I think we heard a couple of comments about some of the quagmires that that kind of plan might lead to, so I think maybe this is worth a bit of thought.

Okay. So from -- my understanding of this is that the proposal is to take foods that are clearly

beneficial, if I'm understanding the intent here, and that have particularly low levels, but that may not -- may still be above the NSRL, but are low relative to other foods, and put them into a category -- a separate

category. And that's my understanding of what the proposed -- the proposal is.

And, Lauren, maybe you want to clarify that.

DR. ZEISE: That's one part of what we potentially could do. Another part would be to take foods for which there was quite a variability in concentration and set a concentration level at a relatively low level and that would turn into an allowable concentration for that specific food type. Things below that concentration level would be exempt.

DR. HERTZ-PICCIOTTO: So the thinking here is that within a type of food, if there is a lot of variability, then it should be possible for those products that are often above -- at the high end to be able to lower those exposures down to the low end.

And I think that certainly the premise of that argument and that proposal is reasonable, and I think there's a lot of information in our packets suggesting that already a number of the European countries have been putting their heads together to try to figure out how to lower exposure levels and have some proposals and ideas for how to do that in their food products.

So this would sort of be an incentive for the industry to look at their processes and use the best available information to move their product down into

that low end.

CHAIRMAN MACK: I have a couple of comments. One of them is that presumably the level of risk, level of exposure is going to depend on the temperature of the cooking process, and I guess some of the logic that's been expressed by some of the conclusions is that this is inversely related to the likelihood of protection against micro -- microbiological contamination. In other words, they're afraid that maybe people will lower temperatures so they all suddenly have contamination.

And I think the two thresholds are so likely to be different that this is just not a rational thing to consider. In other words, one need not be concerned about that. I don't see -- I can't imagine the circumstance in which there would truly be a likelihood of microbial proliferation because somebody tried to avoid the Maillard process.

And then with respect to general nutritional content, that is so food-specific that I think you just get yourself into a complete quagmire.

And in relation to the degree of variation in quantitation and concentration in trying to come up with a concentration level, you're going to have so many

24 different individual circumstances that you have to
25 address that it seems to me that it would be a terribly

1 person-hour intensive process trying to come up with
2 even -- keep up with the methods of measurement, much
3 less deciding what to do once you got the measures.
4 So I think -- and I guess they're all tied to
5 the issue of warning in the first place. And I guess
6 when we get to that, I think we've got to keep in mind
7 what the whole Proposition 65 is all about. It's about
8 trying to inform the public to lower their risk.
9 And we're thinking now that the way to do that
10 is regulating industry by putting out a guideline for
11 them to look after, but that's really not going to make
12 much difference in this particular instance because
13 there's so much variation in home cooking and in
14 cooking -- and in the temperature used by one McDonald's
15 compared to another McDonald's. There's going to be a
16 huge variation.
17 And it's much more important if we could try
18 and get the message to the public that there was a
19 potential risk here as opposed trying to regulate
20 industry. But more about that maybe later.
21 DR. SPANGLER: I just have a question, and
22 there's something that's been bothering me that I don't
23 really understand and maybe somebody can explain it to
24 me, but -- and this may not be the time -- but it has to

do with a conflict in the way the samples are analyzed.

Apparently, there's some -- there's some divergence of opinion because that's one of the things that the fellow from the CLEEN organization mentioned, and it's something that I didn't understand and it's something, obviously, that there's a divergence of opinion between that organization and the way the State might have proposed doing it or -- it's just something that I don't understand, and maybe I'm reading into this something that's not there, but there appears to be a conflict, and is --

DR. ZEISE: Yes, maybe I could again ask Ed Weil to explain this. It has to do with the initial way in which we discussed it in the work plan as something being detected versus detectable, and it is "detectable" in the regulation.

But the issue goes beyond just a difference between the work plan and it was -- and the way it was explained, so Ed.

MR. WEIL: Thank you.

I don't want to get too much in detail into that. I think, in answer to your question, we have a regulation that's pretty complicated, that lawyers argue about all the time in front of judges, and the issue that was brought up by Mr. Schmitz is that the regulation basically talks about saying that, if a

chemical is not detectable, it's treated under the law as if it's not there, which is not necessarily the same thing as saying that the chemical has not actually been detected, because it may be possible to detect it.

But then you get into complicated legal issues about what that means in court and whether you have to have an actual test result in hand in which it was, in fact, detected or you simply need the declaration of a scientist who says, no question, if you run this test, it will be there.

But I -- you know, these are issues that will be addressed as the work plan proceeds and that OEHHA will have to be cognizant of and that will be worked out, and we're very aware of the comments made by CLEEN and we'll try to get that issue resolved and hashed out.

But I think, for purposes of the sentiment of the committee, if there are ideas that the members want to express about what methods ought to be looked at as the most reliable, important, replicable methods to be used, then that would probably be of more guidance to OEHHA staff.

DR. FELTON: Just to comment on that from being in this mess for years, I mean, what you heard from Dr. Shibamoto is exactly where the problem is. It's not in

the GCMS or the LCMS measurements. It's in how you prepare the sample in these real complex foods. So the amount of oils you have and how much starch is present is going to affect your yields in how you do these measurements.

And that's where -- whoever decides is the best method -- is where the real standardization is. The actual analytical tools you use are much more standardized.

DR. HERTZ-PICCIOTTO: Well, it seems to me that this sort of spills over into the other item, No. 2, on the -- and it also, obviously, overlaps No. 4.

So I think maybe we should broaden this out because -- I mean, I think the proposal number -- item No. 3 in the work plan really lends itself to a lot of problems that we can't even fathom at this point, but I think they were sort of hinted at in some of the comments about the -- what may end up being sort of endless debate about what constitutes a bread, what constitutes, you know, a chip.

And I'm not sure that OEHHA really wants to get into that business of classification of foods, although it does seem like a somewhat attractive idea to set up a system that provides for incentives to sort of self-regulate.

On the other hand, I want to go back to the point that Dr. Mack made, and it was also made by one of the -- I think it was the Center for Science in the Public Interest -- that the spirit of Proposition 65 isn't regulation as much as public right to know.

And I think that, with that in mind, that that's really the central question that we should be keeping at the forefront of the advice that we give to OEHHA: How best can the agency keep the public informed in a manner that is useful and not alarming, but at the same time informative and keeps the public as up-to-date as the scientific and regulatory community is.

And I think that's -- that's really the heart of what we should be doing. And I -- in that spirit, I'd actually like to move us to a discussion of No. 4, which certainly has bearing on No. 3, and No. 4 is: What would be the content of any warnings that might go out?

And I would assume that within that we might also want to discuss, you know, what kind of warnings those would be, not just in content but in scope.

Is there going to be a little sign at the fast-food restaurant as you walk in the door? You know, is it going to be up on the menu and so on? But what really is the point that the scientific and public health community would like the public to know?

We have this substance that formerly wasn't known to be present and now we know it's present and we know it is a harmful chemical and it's at levels that are higher than a lot of other things that we have little warning labels out there.

We have little warnings at the gas station when you fill your pump, for those of you not from California, that's been there for 10, 15 years now, and is there a reason not to do that here, and what kind of warning would we want to have?

Could it be a warning that is a little less definitive than the warning labels that are out there because the data itself are less definitive?

CHAIRMAN MACK: Let me address this for a minute and just point out some of the complexities.

If you -- if we do develop methods of measurement which are very precise and if we find that that doesn't turn out to be a problem from -- after a while, there still is going to be incredible variation from food to food and from method of cooking to method of cooking.

So what we're dealing with, as far as I'm concerned, is a global problem. It's not a food-specific problem. It's not a restaurant-specific problem. It's not a method-of-cooking-specific problem

even. It's a general problem.

And informing the public about 4500 different kinds of foods and 350 different kinds of restaurants and cooking methodologies does not seem to be a particularly effective way of informing the public about the danger.

And this, of course, is presuming that there is truly a danger, and I'm accepting the animal studies, I'm accepting the consistency of the thyroid carcinomas and the additional noncarcinogenic problems to suggest there is.

And when I see the estimates that Dale provides, which suggests that there may be -- it might be reasonable to think of molecular analogy between this and other carcinogens and the difference between exposure to very young people and older people and, of course, we know that that's true not just for molecular carcinogens but it's true for radiation and it's true for -- for endocrine exposures as well, I think it's quite reasonable to presume that that's going to be the case.

So there are a few things that we are coming to know about this stuff. We must presume that it's dangerous, we do know that it's probably more dangerous for some people than others, and we know it's all the

hell over the place. And those are the things that I think we've got to try and communicate to the public.

Now, this organization is not the most efficient way to get that kind of a message out because that's not the way you've traditionally tried to handle things.

And maybe you can't do it any other way, but it seems to me that trying to educate the public in a more generic fashion about the global problem is what you want to try and aim for, and whether or not you can do that I don't know.

Maybe the poster like the one on the gas station is not going to be the way to go. Maybe trying to hit the media and trying to put up posters of a much more detailed kind that say -- first of all, recognizes our state of ignorance and, second of all, says the facts that we do have concerns about and the few things that we do know and that people have to pay attention to these things, although there's no particular organization or company or product that specifically can be stated to be the risky one.

I don't know. But I just think that this is a novel problem and we've got to have a novel solution for it, and maybe it isn't even in OEHHA's camp.

DR. HERTZ-PICCIOTTO: Well, that's an

interesting perspective.

Okay. The very last statement you made, though, I think is a little bit counter to the information we saw that suggested that 83 percent of the acrylamide seems to come from eight products, and that would seem to me to be useful information rather than this stuff is all over the place and it's in everything and, you know, that -- which just seems to say, throw up your hands, you can't doing anything about it, you have to eat to live unless, you know, you want to go on some starvation diet so -- and that really is --

CHAIRMAN MACK: Just to be clear, I would certainly include that kind of information that we have as part of the information. I'm not really saying, ladies, it's all over the place.

DR. HERTZ-PICCIOTTO: Right. Okay.

DR. GOLD: Irva, can I just say one thing?

There are people -- limited number of people who are expert in risk communication, and I would suggest that maybe OEHHA, rather than listening to us guess about how to do this, would solicit the input of folks who know how to do it better for such purposes.

CHAIRMAN MACK: I think the only -- I'm not saying what the thing should say. I'm just saying that we're faced with the global problem, not a specific

problem, and I think we've got to recognize that.

Does anybody else want to address that issue?

DR. GOLD: I'm just want to say it's a complicated message, and there are people who are more expert at communicating complex messages to the public than perhaps those of us sitting here.

CHAIRMAN MACK: Joe.

DR. LANDOLPH: Yeah. Based on the -- you know, the animal data, the cancer potency factor of the acrylamide is on the order of that for n-nitrosodiethanolamine -- and there was another compound in there as well -- so it's healthy as a carcinogen based on the animal data, but I share your misgivings.

I'm a little bit worried that the public is getting burn out over stickering everything. I mean, I've gone into grocery stores and seen heads of lettuce stickered, and people will walk by and say, well, what the hell is this? And they don't pay any attention to it.

So I think this requires a lot of thought, and I agree with your comments about using skilled risk assessment communication people because otherwise people are going to lose respect for the stickering and the whole process is going to lose respect, which is the

opposite of what we intended to have.

CHAIRMAN MACK: Any more wisdom from the people up here?

Mr. Roe, would you like to make a comment?

MR. ROE: Thanks. I'm David Roe. I don't represent any group today. I was here as an observer. I suppose I represent one of the original sponsors of Prop 65, meaning myself.

But what I thought I might do is provide just a little general background. It's been long enough that I don't think the last time I addressed this body it had any of its current membership, so at least I represent ancient history.

The most important thing to keep in mind is the difference between the state law that you're operating under and the federal system that Dr. Troxell represents.

What happened in 1986, when the voters passed Proposition 65, was to say that federal system is fine, but it has a weakness, which is that complicated issues of toxics exposure to people can be debated forever, the 25 years that was referred to earlier.

We want one change in California, which is that when the facts get to a certain level, something changes so that the momentum is no longer in favor of endless

debate but in favor of doing something. Not something drastic or definitive but something.

The threshold that was set was the finding that this body makes, which is to a clear scientific

threshold something is determined to be known to cause cancer or reproductive toxicity. That was the threshold in the law.

What happens at that point is not that anything is restricted or banned, but that people who are exposed to that chemical get some information to allow them to make choices about whether they want to continue to be exposed or change their behavior. They're fully entitled to go ahead and keep doing exactly what they were doing but they get some more information.

Now, that's not an ultimate solution to any particular problem of toxic chemical exposure. It's a weigh station.

The reason that it has been important and the reason it was intended to be this is that it changes the momentum. It creates momentum in favor of getting to the ultimate solution, of getting more information, of accelerating the process, of filling out the data cards, filling in the data gaps, learning what it is that you don't already know.

So my strongest piece of advice to this group

is, make out your wish list, because you're operating under a law where no longer is it your burden or FDA's burden or the state government's burden to have to come up with all of the science.

You've now engaged the constituency that's

economically involved, that is involved in manufacturing, selling and profiting from particular products in private commerce. Now it's in their interests to fill you in.

And the highest service you can perform for OEHHA at this juncture is to be as clear as possible of what it is you would want to know or what it is that OEHHA ought to want to know in order to take any of the proposed actions that are in the work plan, all of which seem to me to be appropriate to explore. Perhaps not all appropriate to take, depending upon the scientific outcome, but certainly all appropriate to explore.

So all I really wanted to suggest was there was a sea change when this law passed, but the sea change was simply to change the momentum, once you got to a threshold about where the science was going to come from, where the momentum was going to come from to get to a satisfactory ultimate solution about any particular chemical and set of exposures. That's where you sit now.

There's nothing new about the situation that you face with acrylamide. There's nothing new about a chemical that's been long listed that turns out to have odd manifestations or unexpected manifestations.

Lead was listed in the original list of only 29 chemicals. People at the time didn't expect that it

would show up in dishes or tea cups or calcium supplements or faucets.

And, indeed, when it did, people said, do you know what the public health consequences will be if people can't have running water or will eat off of paper -- dirty paper plates? None of those, of course, came to pass.

What makes this, of course, interesting and complicated and worth all this attention is there are so many new places and so many different food products, and the weigh station solution of a warning is one which the industries involved view with great alarm. They certainly don't want to provide that weigh station on the way to figuring out the ultimate solution.

But that is, indeed, what creates the incentive to bring forward information. And, again, I suggest if you can provide with -- OEHHA with the clearest possible sense of what it ought to know scientifically, that's a major service.

One other comment on Dr. Mack's suggestion of risk communication -- I'm sorry -- Dr. Gold's suggestion of risk communication.

This, too, is a very old theme; and when the law was originally passed, there was a good deal of discussion about how warnings should go on at great length and be hand-tailored to each individual situation

and essentially recapitulate the full complexities of the science in each context.

And the decision very sensibly was made, no, that's not what this law is about. It's an on-off switch. It may not be a perfect on-off switch, but it has a purpose, and that purpose is best served by a fairly simple, clear, unadorned communication.

There were a number of risk communication experts that testified to a room with 600 people in it and your predecessors sitting up at the table making the opposite point. I just provide that to you as a piece of historical perspective.

Obviously, this will come up again as the regulatory process goes on, but I just wanted to give you a little flavor for where we've already been.

And I'm happy to answer questions, but I'm also grateful for the opportunity to relive old history.

CHAIRMAN MACK: I think you should probably

present yourself every couple of years at a very minimum because I think it's a very useful story for us to hear.

Does anybody have any questions for Mr. Roe?

I would say that this situation may be different than almost every other one that we've passed, and it may be that we have to get into more complexity, although if we could think of a way to avoid it, I'm

sure we would all jump at it and maybe we can.

MR. ROE: I think this will play out, but I'm suggesting there is something to be learned from the successful history so far. Many crises have been predicted that have not come to pass.

Thank you.

DR. HERTZ-PICCIOTTO: Well, I'm going to sort of --

MR. WEIL: Excuse me. I'm sorry to interrupt, but we really need to take a 15-minute break for the court reporter. It's necessary at this point.

CHAIRMAN MACK: We'll take a break for how many minutes?

MR. WEIL: Fifteen.

CHAIRMAN MACK: Fifteen.

(Recess taken.)

CHAIRMAN MACK: Can we get started again and

catch up with this.

DR. HERTZ-PICCIOTTO: We're running late here and not quite at the closure point, so let me make a proposal here in regard to this general problem and give a broad view of what I think maybe the committee might -- and you can modify -- other members of the committee can modify this -- but I think what we'd like to advise is that OEHHA take responsibility for a public health education effort and that the emphasis here is on

education, which includes educating the public about uncertainty and incompleteness of data, but at the same time emphasizes what we do know.

And without spelling out all the details of what we do know, we do know that acrylamide is a carcinogen and we do know that it is present in certain foods at levels that we can give some ballpark estimates of and that there are certain food groups -- maybe they're the eight we saw on a slide earlier today or maybe it's a slightly modified version of that -- but there are certain food groups or types of food or food prepared in certain ways that are the bad actors, and that based on the recognizably incomplete information, this -- these levels of acrylamide may pose a risk -- a significant carcinogenic risk.

I think part of the message also needs to state

that the State of California is working with national and international agencies to gather more information and that that scientific information will be used to update on a regular basis the information that goes into these public health messages and that this is a dynamic situation, which is a good thing.

And I think we shouldn't fear the fact that we will put out a message today that will have to be modified. That's the state of science and it's the state of the world. Things are always changing and

things -- and our knowledge is changing.

But I think that this would be a wise way to proceed, and the specifics, you know, of how to carry out that education campaign, I think, I'd leave up to OEHHA.

And there's been some very creative ways in which Californians have been informed about risks, and I'm thinking of the -- our smoking education campaign. So I think we can use the creativity that we have here to devise that kind of a public education campaign.

So that would address, I think, the issue of the work plan -- some of the work plan questions that are out there.

And, again, I would emphasize that this would be a dynamic campaign with changing -- with message --

the message updated on a regular and not too infrequent basis, and I think the agency can think about how frequently that could be done in a realistic way without falling behind the science.

CHAIRMAN MACK: Okay. Does anybody else have any comments?

This is, obviously, a very broad piece of advice. I would also mention the age, but I think you will probably do that without me mentioning it, the fact that children and pregnant women may be more pertinent.

Jim.

DR. FELTON: So what's the alternative to that? Would it be to say, yes, we feel the agency should be giving advice to the public, but let's wait until the FDA NTP study is in for more confirmation of the animal data? Or do we say we go with what we have -- I guess we go with what we have now and then we update it? I mean, that's sort of the two alternatives.

CHAIRMAN MACK: I think the big difference between what she's outlined and what we normally would expect OEHHA to do is that there's less emphasis on the regulation of the regulated community and demands that they meet a specific level because we don't know quite how to make that work easily and we don't know how to be equitable in that kind of a mandate.

So the global warning is a different issue than having a small label on every loaf of bread that goes into the grocery store.

DR. HERTZ-PICCIOTTO: Well, I -- on the one hand, you're posing it as it's so global it's -- the emphasis is not on regulation.

On the other hand, I would think that we would expect the acrylamide levels to be reduced using the information that is coming in, and quite clearly there are a large number of studies and many of them are examining ways to reduce acrylamide formation in the production of the food supply, so it would seem to me

that there is some incentive here in general for that reduction.

And that -- I would hope that the message that the food industry would take home would not be that, oh, they needn't worry and -- in fact, you know, if it turns out that certain foodstuffs are staying way up at the high levels when methods are out there to lower them, then that could end up going into the messages that would come out in two or three years from now.

And in other words -- that's how I would picture this. That this -- at this point, there's a lot of uncertainty, and at the same time I think there is a lot of hope that levels can be brought down based on the

research that's going on, and I would expect that that would be taken to heart.

CHAIRMAN MACK: Obviously, that policy would be re-assessed from period to period, and one would expect that the marketplace and the litigation environment would both be motivators for food industry to bring down the levels to the extent that they can.

And the marketplace, however, is a function not only of risk but of the desirability of taste, and in this particular case that's a very complex issue and that's one of the things that makes it so difficult to regulate.

But if it turns out that after a year or two

the levels that are being measured, and more accurately by then, are even higher or as high as they are now, then maybe every assessment by OEHHA will take place. So one -- one just doesn't know.

DR. GOLD: Just one comment. I wonder if we might ask that periodically, I don't know, once a year or something, that OEHHA would sort of update the committee on the progress on their work plan so that if we run into this situation ever again we might be informed by how it progressed.

CHAIRMAN MACK: Yeah, I think that's like -- something we really would like to have.

Are we finished? We have no mandate to structure a formal recommendation with voting, so I gather the information that was suggested is duly recorded.

DR. DENTON: I would like to summarize your recommendations and see if this is, in fact, what the consensus is of the committee so that we're clear.

You are recommending, first of all, that we go ahead and revise the current NSRL, and in that -- in that revision, you had a -- you were recommending appropriate caveats, for example, using the human data to set an upper bound estimate, that sort of thing.

The second thing is that you -- you did endorse the idea at least of the second part of the work

plan, and that is -- second step, and that is defining the methods of detection, but with the caveat that there's a lot of sampling and measurement variability.

On the third part of the plan, which was setting alternative risk levels for categories of foods, you are recommending that we don't do that, but instead craft a global generic warning in the spirit of the right to know intention of Prop 65.

You are also recommending that we undertake a public education -- health education effort in which we would be devising public health messages with the

intention that it would be an education campaign and that it would be a dynamic education campaign in that, as more information was available, that these public health messages would be updated.

And then, finally, you are recommending that we periodically update you on the progress of this effort.

CHAIRMAN MACK: I'm not sure I get the distinction between the warning and the public health message. I'm not sure where the warning is going to go. If you had in mind that we wanted you to have a warning in every shop and every grocery store, I don't know if that was true.

I think that it might be one form that the public health messages could take, but I don't really think we have any wisdom to provide about that.

And I would just make one statement -- I think everybody would agree with it -- when we say that the -- that the message -- the public health message goes out, it isn't something as bland as, have a good balanced diet, as the FDA would propose. It's a little more specific than that, mentioning specific foodstuffs in the context of this particular chemical.

DR. DENTON: So if I could revise that then, it's -- actually, you are recommending a public health education effort which would be devoted to this whatever

kind of global or generic language that we come up with? Is that essentially it?

CHAIRMAN MACK: That's kind of what I had in mind. I don't like to use the word "global." I don't really think that's a good word. A warning with respect to the dangers of this particular chemical which is -- goes out to the population in general. And while it mentions certain foods, it isn't tied to -- necessarily to any company or --

DR. HERTZ-PICCIOTTO: I would -- yes, I would want to see the foods -- the particular kinds of foods -- you know, chip, fries, we know those are among the high ones, coffee -- brewed coffee, and as that list becomes more -- clearer as more data come in, then that would be fine.

And I would also include in this message that

we are talking about a cancer risk very specifically, and I -- it's not for us to say about reproductive harm, but I would strongly suggest that that question be put before the DART Committee, if it's not already part of -- if that's not already in the works.

And I don't know if there's a mechanism for addressing neurotoxicity through the state at all, but I would think that that should also be considered, although it's a -- it's got its own complications, and

I'm not proposing that as part of this message.

DR. DENTON: Just regarding the DART Committee, actually, the listing -- potential listing is actually an administrative thing which wouldn't go to the DART Committee, which actually is an OEHHA function, but we also are aware of the neurological endpoint that appears to be the one of concern which could be crafted as part of this message.

CHAIRMAN MACK: I don't think she was -- I guess what she was asking was whether or not they had specifically looked at reproductive problems from this chemical.

DR. DENTON: Has the DART Committee?

CHAIRMAN MACK: Yeah.

DR. DENTON: No. No. It --

CHAIRMAN MACK: Is there any plan to do that?

DR. DENTON: It's -- the listing -- the listing

for acrylamide for cancer was through an authoritative bodies mechanism, and that would be the same potential mechanism for the DART Committee.

So your committee didn't see the -- your committee didn't opine on the listing for cancer and, similarly, you know, it would be another mechanism -- another mechanism is employed is the --

CHAIRMAN MACK: I understand that, but you came

to us for a discussion of the process of the work plan, and so we're asking, should there not be consideration given to the involvement of the DART Committee in the work plan for the same reason?

DR. DENTON: Well, it's not on the -- on the DART Committee's -- it's not on the reproductive list. And, also, it seems to be a neurological endpoint, again, as the sensitive endpoint and not a developmental.

Isn't that correct? No?

DR. FELTON: The researchers at our lab use acrylamide as their positive control in their male toxicity studies, so it's a great male teratogen.

CHAIRMAN MACK: They might mention that to the DART Committee.

DR. HERTZ-PICCIOTTO: Well, I would wonder if that also should in some way enter into the public education campaign.

DR. SPANGLER: And the message that is in this public education campaign will necessarily have to include -- mention that the largest exposure that one is apt to see of acrylamide is going to occur in their own kitchens.

DR. GOLD: So are we saying then in the message, therefore, there might be something particular

for children and/or pregnant women potentially? It's something that OEHHA ought to consider in their message? They've done it for other things. They might consider it for this.

CHAIRMAN MACK: I specifically would suggest that.

DR. HERTZ-PICCIOTTO: And just going back to the medium, as opposed to the message, I would like to see television used in this effort to educate people since probably the overwhelming --

DR. DENTON: Lauren's budget. Lauren, can you -- poor Lauren and her budget.

DR. ZEISE: Yeah, I just wonder if the new governor could help us out with some of this.

DR. HERTZ-PICCIOTTO: Well, isn't there -- aren't there legal requirements for public service announcements of some sort?

CHAIRMAN MACK: Okay, I think we've completed -- we certainly haven't provided any wisdom

but we've provided a forum. It's been educational to me at least.

Thank you for your participation.

DR. DENTON: Wait. We have some updates.

Cindy, I think you're up.

MS. OSHITA: As has been my usual role, I've